

**MECLIZINE HCL 12.5 MG- meclizine hcl 12.5 mg tablet**  
**Northwind Pharmaceuticals**

*Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.*

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**Meclizine HCL 12.5**

***Drug Facts***

***Active ingredient (in each caplet)***

Meclizine HCL 12.5 mg

***Purpose***

Antiemetic

***Uses***

- prevents and treats nausea, vomiting, or dizziness due to motion sickness
- for other uses, consult your doctor

***Warnings***

**Ask a doctor before use if you have**

- glaucoma
- a breathing problem such as emphysema or chronic bronchitis
- trouble urinating due to an enlarged prostate gland

**Ask a doctor or pharmacist before use if you are** taking sedatives or tranquilizers

**When using this product**

- you may get drowsy
- avoid alcoholic drinks
- alcohol, sedatives and tranquilizers may increase drowsiness
- be careful when driving a motor vehicle or operating machinery

**If pregnant or breast-feeding,** ask a health professional before use.

**Keep out of reach of children.** In case of overdose, get medical help or contact a Poison Control Center right away.

**Ask a doctor before use if you have**

- glaucoma
- a breathing problem such as emphysema or chronic bronchitis
- trouble urinating due to an enlarged prostate gland

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- you may get drowsy
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If **pregnant or breast-feeding**, ask a health professional before use.

**Keep out of reach of children.** In case of overdose, get medical help or contact a Poison Control Center right away.

### Directions

- **adults & children 12 years and over:** 2-4 caplets once daily
- **children under 12 years:** ask a doctor

### Other information

- **each caplet contains:** calcium 51 mg
- store at room temperature 15°-30°C (59°-86°F)
- This is a bulk package. Dispense contents with a child-resistant closure in a tight, light-resistant container as defined in the USP.

### Inactive ingredients

croscarmellose sodium, dicalcium phosphate, magnesium stearate, microcrystalline cellulose, silicon dioxide, stearic acid

### Questions or comments?

call **516-341-0666**, 8:30 am - 4:30 pm ET, Monday - Friday

Distributed by: **Reliable 1 Laboratoires LLC, Valley Stream, NY 11580**

**www.reliable1labs.com**

**TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING**

### Principal Display Panel

NDC: 51655-428-53



## MECLIZINE HCL 12.5 MG

meclizine hcl 12.5 mg tablet

### Product Information

Product Type		HUMAN OTC DRUG	Item Code (Source)	NDC:51655-428(NDC:69618-027)		
Route of Administration		ORAL				
Active Ingredient/Active Moiety						
Ingredient Name			Basis of Strength		Strength	
MECLIZINE HYDROCHLORIDE (UNII: HDP7W44CIO) (MECLIZINE - UNII:3L5TQ84570)			MECLIZINE HYDROCHLORIDE		12.5 mg	
Inactive Ingredients						
Ingredient Name				Strength		
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)						
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)						
MAGNESIUM STEARATE (UNII: 70097M6I30)						
STEARIC ACID (UNII: 4ELV7Z65AP)						
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)						
CALCIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: L11K75P92J)						
Product Characteristics						
Color	white	Score	2 pieces			
Shape	OVAL	Size	13mm			
Flavor		Imprint Code	AP;117			
Contains						
Packaging						
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:51655-428-53	10 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	09/01/2020			



# MECLIZINE HCL 12.5 MG CAPLET

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part336	09/01/2020	

**Labeler** - Northwind Pharmaceuticals (036986393)

**Registrant** - Northwind Pharmaceuticals (036986393)

## Establishment

Name	Address	ID/FEI	Business Operations
Northwind Pharmaceuticals		036986393	repack(51655-428)